

## Interview Summary

Application No.

09/214,723

Applicant(s)

OKA, TAKANORI

Examiner

Bradley L. Sisson

Art Unit

1655

All participants (applicant, applicant's representative, PTO personnel):

(1) Bradley L. Sisson.

(3) \_\_\_\_\_

(2) Kristi Rupert, Ph.D., Reg. No. 45,702.

(4) \_\_\_\_\_

Date of Interview: 03 January 2001.

Type: a) ☐ Telephonic b) ☐ Video Conference  
c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.

If Yes, brief description:

Claim(s) discussed: 2-10, 12, and 13.

Identification of prior art discussed: Levi et al., Cancer Research, Vol. 51, pp. 3497-3502, July 1, 1991; WO 95/02068; and "A supplementary explanation of the present invention" provided by applicant.

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☒ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

B. L. Sisson  
Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

#### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

##### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

##### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

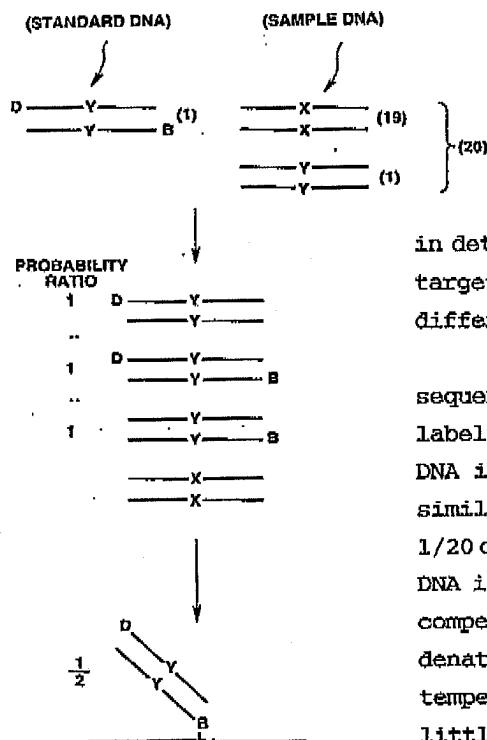
Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Agreement was reached that the specification needs to provide antecedent support for the mathematical formulas recited in the claims. Mr. Sisson noted that while original claim 2 provides literal support for such formulas now found in claim 13, he could not locate support for such in the body of the specification.

Mr. Sisson expressed concern over how the claimed method appeared to be a combination of polymerase chain reaction and competitive hybridization reaction. Agreement was reached in that both of these methods were known in the art at the time of filing. Mr. Sisson directed attention to applicant's PCT publication WO 95/02068 which seemed to suggest the claimed invention.

# A supplementary explanation of the present invention

In order to judge between the presence and absence of the target DNA and quantitating the target DNA including in an analyte nucleic acid of a specimen which is the same as a labeled standard DNA, a labeled standard DNA comprising a double stranded nucleic acid having a site capable of binding to a solid support on one strand and a detectable label on the other strand is prepared. Also, the particular region of the analyte nucleic acid in the specimen is amplified to prepare a double stranded sample DNA having the same region as the labeled standard DNA.



The present invention is described as follows in detail by considering the case of coexistence of the target DNA and the similar DNA which is slightly different from the target DNA.

When the content of the target DNA (or the target sequence) in the sample DNA which is the same as the labeled standard DNA is 5% (In other words, the sample DNA is the mixtures of the target DNA of 5% and the similar DNA of 95% .), the amount of the target DNA is 1/20 of the sample DNA. The amount 20 times of the sample DNA is added to the labeled standard DNA and then the competitive hybridization is promoted after thermal denaturation of the DNA by gradually reducing the temperature from the high temperature. In this case, little exchange reaction of the complementary strands

between the similar DNA and the labeled standard DNA brings about. However, the exchange reaction of the complementary strands between the target DNA being the amount 1/20 of the sample DNA and the labeled standard DNA brings about. That is, the sample DNA is exchanged in the equal amount ( $20 \times 1/20 = 1$ ) to the amount of the labeled standard DNA, which is the amount 1/20 of the sample DNA added in the amount 20 times. Therefore, the amount of the labeled standard DNA rehybridized is expected to be about 1/2 of the amount of the original sample and then the absorptivity is expected to become about 1/2 of the amount of the original amount.

As described above, when the proportion of the target DNA in the sample DNA which is the same as the labeled standard DNA is  $A/B$ , the sample DNA of the amount  $B/A$  is added. As a result, the amount of the labeled standard DNA rehybridized is expected to be about  $1/2$  of the amount of the original sample. Specifically, according to a nucleic acid assay process of the present invention, the drop of the label intensity (absorptivity) which become half makes it significant to assay the target DNA and thus the sample of the amount of at least  $B/A$  is added when the proportion of the target DNA in the sample DNA is expected to be  $A/B$ .